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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,817	03/27/2006	Walter Gumbrecht	32860-00901/US	1151
30596	7590	12/10/2007		
HARNESS, DICKEY & PIERCE, P.L.C. P.O.BOX 8910 RESTON, VA 20195			EXAMINER EDWARDS, LYDIA E	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,817	GUMBRECHT ET AL.	
	Examiner	Art Unit	
	Lydia Edwards	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/20/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/20/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 7 and 15, the phrase "pointlike" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albers et al. (WO 00/62048) in view of Frazier et al. (US 6169394). Regarding Albers et al. (WO 00/62048), which was not published in English, the US equivalent US 7208077 was used as an English translation.

Regarding Claim 1, Albers et al. ('077) does not specifically disclose two polarization and two sensor electrodes but does disclose an analogous thin film DNA chip, comprising: a carrier and, arranged thereon, a microarray of spots, arranged on the carrier containing immobilized catcher molecules, each spot containing a thin-film four pole system for the impedance-spectroscopic detection of binding events between the catcher molecules and target molecules of an analyte solution applied to the spots (Col 5, lines 49-54; Col 6, lines 14-25; Col 15, lines 28-35; Col 23, lines 10-48).

Frazier et al ('394) discloses a microchip containing a thin-film four-pole system, including two polarization electrodes for generating an alternating electromagnetic field and two sensor electrodes for measuring a voltage drop in the analyte (Col 8, lines 39-65; figure 3a). The reference uses the terms detector and reservoir electrode of which the examiner deems to be equivalent to sensor and polarization electrode.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Albers et al with a thin-film four-pole system, including two

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polarization electrodes and two sensor electrodes as taught by Frazier et al. in order to provide a means for probing biological materials for pathogenic organisms and molecules.

Regarding Claim 2, Albers et al ('077) discloses a microchip wherein the carrier includes a silicon substrate on which the microelectrode system is integrated using thin-film technology (Col 6, lines 29-36).

Frazier et al ('394) also discloses a microchip wherein the carrier includes a silicon substrate on which the microelectrode system is integrated using thin-film technology (Col 9, lines 43-55).

Regarding Claim 6, Frazier et al ('394) discloses , wherein at least one of at least one sensor electrode and at least one shielding electrode are directly electrically isolated from the analyte (Col 8, lines 39-65 and figure 3A).

It would have been obvious to one having ordinary skill in the art at the time the invention made to modify Albers et al. to allow for direct electric isolation as taught by Frazier et al. in order to prevent any unexpected charge.

Regarding Claim 7, Frazier et al ('394) discloses wherein a sensor electrode contains pointlike individual electrodes which are electrically connected to a buried electrode collective line by way of plated-through holes. (Col 7. line 53-Col 8, line 53; figure 2b).

It would have been obvious to one having ordinary skill in the art at the time the invention made to modify Albers et al. with pointlike individual electrodes which are electrically connected to a buried electrode collective line by way of plated-through holes as taught by Frazier et al. in order to form a detection zone for interrogation of test samples.

Regarding Claim 8, Albers et al ('077) discloses wherein the thin-film microelectrode system is embedded in a reaction layer containing catcher molecules (Col 23, lines 21-48).

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Regarding Claim 9, Albers et al ('077) does not specifically disclose wherein the thickness of the reaction layer is less than 100 micrometer and is correlated with the width of the electrodes or the interspaces thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a reaction layer of reasonable size in respect to the width of the microfluidic device, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ

Regarding Claim 10, Albers et al ('077) does not specifically disclose wherein the width of the electrodes is approximately 1 micrometer, and the thickness of the reaction layer corresponds to approximately 5-10 times the value of the electrode width.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to design an electrode of reasonable size to provide a portable biosensor system for the rapid detection of pathogenic bacteria, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ

Regarding Claim 11, Albers et al ('077) discloses wherein the reaction layer is a hydrogel (Col 23, lines 10-48).

Regarding Claim 12, Albers et al. ('077) discloses wherein the thin-film four-pole system forms an interdigital current electrode arrangement with double meandering current taps (Col 12, line 66-Col 13, line 4).

Regarding Claim 14, Frazier et al ('394) discloses , wherein at least one of at least one sensor electrode and at least one shielding electrode are directly electrically isolated from the analyte (Col 8, lines 39-65 and figure 3A).

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It would have been obvious to one having ordinary skill in the art at the time the invention made to modify Albers et al. to allow for direct electric isolation as taught by Frazier et al. in order to prevent any unexpected charge.

Regarding Claim 15, Frazier et al ('394) discloses wherein a sensor electrode contains pointlike individual electrodes which are electrically connected to a buried electrode collective line by way of plated-through holes. (Col 7. line 53-Col 8, line 53; figure 2b).

It would have been obvious to one having ordinary skill in the art at the time the invention made to modify Albers et al. with pointlike individual electrodes which are electrically connected to a buried electrode collective line by way of plated-through holes as taught by Frazier et al. in order to form a detection zone for interrogation of test samples.

Regarding Claim 16, Albers et al ('077) discloses wherein the thin-film microelectrode system is embedded in a reaction layer containing catcher molecules (Col 23, lines 21-48).

Regarding Claim 17, Albers et al ('077) discloses wherein the reaction layer is a hydrogel (Col 23, lines 10-48).

Regarding Claim 18, Albers et al. ('077) discloses wherein the thin-film four-pole system forms an interdigital current electrode arrangement with double meandering current taps (Col 12. line 66-Col 13, line 4).

Claims 3-5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albers et al. (WO 00/62048) in view Frazier et al. (US 6169394) as disclosed above in claim 1, and further in view of Gau (WO 01/183674).

Regarding Claim 3, Albers et al ('077) does not disclose a shielding electrode. However, it is well known in the art that a reference electrode of which the examiner deems to be equivalent to a shielding electrode performs the same function as described in Gau ('674)

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wherein at least one working electrode which is equivalent to a sensor electrode is assigned a reference electrode, which is used to control the potential differences between the working electrode and the reference electrode (Page 2, lines 24-38; Pages 9-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a reference electrode for the shielding of Albers et al. to provide a means of maintaining a leveled potential between the sensor electrode and the shielding electrode.

Regarding Claim 4, Albers et al ('077) does not disclose, wherein the electrical potential of the sensor electrode is held at the shielding electrode by a buffer amplifier connected to the sensor electrode and having a gain of 1.

Gau ('674) discloses wherein the electrical potential of the working electrode is held at the reference electrode by a buffer amplifier connected to the working electrode and having a gain of 1 (Page 1, lines 24-38 and figure 1).

It is well known in the art that if the voltage transferred is unchanged, then there is a gain of 1 and the amplifier is a unity gain buffer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Albers et al. with a buffer amplifier as taught by Gau in order to ensure that the required cell polarization is achieved and maintained.

Regarding Claim 5, Albers et al ('077) does not disclose, wherein the buffer amplifier is integrated on the carrier.

Gau ('674) discloses wherein the buffer amplifier is integrated on the carrier (Abstract and figure 1-2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Albers et al. with a buffer amplifier integrated on the carrier as taught by Gau in order to provide rapid detection of pathogenic bacteria in addition to portability of the biosensor system.

Regarding Claim 13, Albers et al ('077) does not disclose a shielding electrode. However, it is well known in the art that a reference electrode of which the examiner deems to be

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equivalent to a shielding electrode performs the same function as described in Gau ('674) wherein at least one working electrode which is equivalent to a sensor electrode is assigned a reference electrode, which is used to control the potential differences between the working electrode and the reference electrode (Page 2, lines 24-38; Pages 9-10).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a reference electrode for the shielding of Albers et al. to provide a means of maintaining a leveled potential between the sensor electrode and the shielding electrode.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lydia Edwards whose telephone number is 571.270.3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

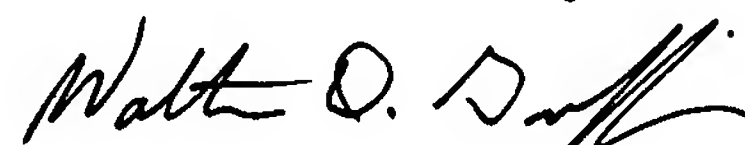
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Lydia Edwards

Examiner

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LE



WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER